

CIRM Funded Clinical Trials

Phase 2 Safety and Efficacy Study of CLBS03 Autologous T-Regulatory Cells in Adolescents with Recent Onset Type 1 Diabetes Mellitus

Disease Area:	Type 1 diabetes
Investigator:	Douglas Losordo
Institution:	Caladrius Biosciences
CIRM Grant:	CLIN2-09730
Award Value:	\$12,211,255
Trial Sponsor:	Caladrius Biosciences
Trial Stage:	Phase 2
Trial Status:	Active, not recruiting
Targeted Enrollment:	113
ClinicalTrials.gov ID:	NCT02691247



Douglas Losordo

Details:

Children with type 1 diabetes (T1D) face lifelong struggles with controlling their blood sugar levels and, despite careful management, an increased risk of severe complications. Currently, there is no approved therapy that maintains or restores the insulin-producing pancreatic beta cells that are destroyed by this disease. Researchers at Caladrius Biosciences will take cells, called regulatory T cells (Tregs), from the patient's own immune system, expand the number of those cells in the lab and return them to the patient to reduce the autoimmune attack on the insulin-producing cells in people with type 1 diabetes.

Design:

Prospective, randomized, double-blinded, placebo-controlled, proof-of-concept study.

Goal:

Primary: Safety. Secondary: Efficacy.

Updates:

Enrolling; Fast track and Orphan designations.

News Releases:

Caladrius Biosciences Awarded \$12.2 Million Grant from CIRM in Support of Phase 2 Clinical Trial of CLBS03 to Treat Type 1 Diabetes
Caladrius Biosciences Announces Completion of Enrollment of Phase II T-Rex Clinical Trial of CLBS03 for Type 1 Diabetes

[Contact Trial Sponsor](#)

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